

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION,
OPIATE LITIGATION

MDL NO. 2804

THIS DOCUMENT RELATES TO:

Case No. 17-MD-2804

Judge Dan Aaron Polster

Salmons v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45268;

Flanagan v. Purdue Pharma L.P., et al.
MDL Case #1:18-OP-45405

Doyle v. Purdue Pharma L.P., et al.
MDL Case No. #1:18-op-46327

Artz v. Purdue Pharma, L.P., et al.
MDL Case No. #1:19-op-45459

NAS GUARDIAN PLAINTIFFS' MOTION TO COMPEL

Guardians of Children Diagnosed with Neonatal Abstinence Syndrome (“NAS Guardian Plaintiffs”), by and through the undersigned Counsel, hereby respectfully move pursuant to this Court’s Order [Rec. Doc. 2738] dated October 7, 2019, and Fed. R. Civ. P. 26, to compel responses to written discovery propounded on Defendants on October 15, 2019. At issue are extremely limited discovery requests related to class certification that fall into two categories:

1. Prescription records that relate to the specific Plaintiffs in the four putative class certification cases; and
2. Documents related to certain clinical studies conducted by Defendants.

Defendants have refused to provide any documents responsive to Plaintiffs' requests, and have instead generally directed NAS Guardian Plaintiffs to Defendants discovery previously produced to the Plaintiffs' Executive Committee ("PEC"), without specifying the location of responsive documents.

NAS Guardian Plaintiffs respectfully request relief for resolving discovery issues "that deprive Plaintiffs of a full opportunity for discovery", and to "identify that additional discovery that might allow Plaintiffs to identify and certify a class", pursuant to the 6th Circuit Court decision in *Doe v. City of Memphis*, No. 18-5565, 2019 WL 2637637 (6th Cir. June 27, 2019). The NAS Plaintiffs have discovery issues that must be resolved by this Court in a timely fashion, and in a manner that will meet the Court's obligations under *Doe v. City of Memphis*, No. 18-5565, 2019 WL 2637637 (6th Cir. June 27, 2019). For the reasons set forth below, and set forth in the supporting Declaration and supporting Exhibits, this Court should compel a response to NAS Guardian Plaintiff's discovery requests.

I. BACKGROUND

On October 7, 2019, NAS Guardian Plaintiffs filed amended class action complaints [September 17, 2019 Non-Document Order] on behalf of children who suffer from Neonatal Abstinence Syndrome ("NAS"). Pursuant to this Court's scheduling order, the parties are preparing to litigate certification of these classes before the years' end.

On July 11, 2019, this Court ruled that "the undersigned is willing to grant Plaintiffs an abbreviated period to review the available discovery, but absent some showing that the available discovery is insufficient, the Court declines to grant Plaintiff additional discovery at this time". [Rec. Doc. 1829] (emphasis added).

NAS Plaintiffs' Efforts to Access and Review Discovery

NAS Guardian Plaintiffs have sought discovery for well over a year. Although NAS Guardian Plaintiffs spent a year and a half working through the process, waiting for data, discovery and filings, and agreeing to execute acknowledgements of and consent to protective orders, as well as PEC imposed participation agreements, NAS Plaintiffs' access to information was delayed, and the information ultimately provided was limited and insufficient.

Contrary to the earlier understanding of the Court, NAS Guardian Plaintiffs had not had access to the Defendants' discovery provided to the PEC. On July 10, 2019, NAS Guardian Plaintiffs delivered a letter to both Plaintiffs' Liaison Counsel, and the Special Masters, advising them that the NAS Guardian Plaintiffs still have not received the Defendants' discovery. The PEC first shared access to ARCOS as of July 12, 2019, notwithstanding this Court's prior order granting access on June 24, 2019. *See* NAS Guardian Plaintiffs' Motion to Modify Protective Orders re DEA's ARCOS/DADS Database [Rec. Doc. 1704] – Granted on June 24, 2019, Order [Rec. Doc. 1725]. Also, on July 12, 2019, the PEC finally shared access to the non-ARCOS discovery documents and transcripts by delivering the Relativity Database.

On July 22, 2019, NAS Guardian Plaintiffs requested an expedited case management conference to resolve outstanding discovery issues that deprive Plaintiffs of a full opportunity for discovery and, also, to identify that additional discovery to allow Plaintiffs to identify and certify a class. Because the discovery, including ARCOS data, had not been available until July 12, 2019, it was both unfair and unreasonable to assume that the NAS Guardian Plaintiffs would be able to properly review and evaluate what additional discovery will be necessary until such time as all material and relevant search terms are run, the NAS Guardian Plaintiffs have an

opportunity to review in excess of 130-150 million pages of discovery, and other formal discovery documents and sealed documents that were to be made available for the NAS Guardian Plaintiffs' review.

On July 26, 2019, in its Order Regarding NAS Guardian Plaintiff Motions [Rec. Doc. 2030] this Court recognized that the NAS Guardian Plaintiffs' Counsel stated that they had "not received sufficient discovery". This Court ordered:

"This Court also makes clear that all Counsel of record for the NAS Baby [NAS Guardian] cases are entitled to review all formal discovery requests and responses, all existing discovery, and any documents that have been placed under seal, once Counsel has signed any required protective orders and discovery sharing agreements. The PEC shall undertake to provide this access to NAS Baby Counsel as soon as possible".

July 26, 2019 Order Regarding NAS Motions, [Rec. Doc. 2030] (emphasis added).

Since obtaining access to the discovery, NAS Guardian Plaintiffs' Counsel have diligently worked with PEC Counsel to receive all the ordered documents which were to be produced in tranches. Over the past three months, a team of attorneys have reviewed millions of documents and Relativity Data, and were unable to locate the formal discovery ordered to be produced. After making their best efforts to search through that massive 30 million document database, NAS Guardian Plaintiffs' Counsel found some of the "formal discovery", but were unable to identify the complete set of formal discovery, except those fragmented segments located in different locations across the massive database.

Declarations were made by the PEC and Plaintiffs' Liaison Counsel that the NAS Childrens' Guardians' interests were being protected, but as of September 12, 2019, NAS Guardian Plaintiffs had not received any of the discovery requests and responses, and the 30(b)(6) notices addressing the NAS Guardian issues.

It wasn't until Monday, September 16, 2019 at 9:29 pm did NAS Plaintiffs receive an email link to a collection of discovery issued by the PEC and formal written responses by a number of the Defendants.

Since only July 12, 2019, NAS Guardian Plaintiffs' Counsel has had access to a collection of 160,000,000 pages of documents provided by the Defendants in response to discovery propounded by the PEC in cases brought on behalf of local governments. Initial review of such documents revealed that the PEC's discovery efforts did not yield documents or testimony related to the medical issues implicated in the NAS Guardian Plaintiffs' putative class actions but, without the underlying discovery requests not received until September 16, 2019, it was impossible to issue new discovery without the risk of retreading ground already plowed by the PEC. Only in the past weeks were NAS Guardian Plaintiffs given access to formal discovery requests and responses as well as 30(b)(6) deposition notices.

Plaintiff-Specific Records and Key Medical Evidence Have Not Yet Been Disclosed

While the collection of discovery provided remains incomplete,¹ the discovery provided were sufficient to identify areas of inquiry germane to medical monitoring that were either not propounded or that the responses were inadequate for the medical monitoring issues presented by the above-styled cases. It is not surprising that the PEC discovery did not delve into these issues of medicine and science. Cities and counties are claiming economic damages, while the claims here stem from complex medical issues.

¹For three defendants, folders for the discovery were empty. For at least fourteen defendants, the PEC provided their discovery requests but not the Defendants' responses. For four defendants, responses and objections to 30(b)(6) notices were missing. Motley Rice was notified of these deficiencies on September 18, 2019 and we are awaiting a response.

By way of example, below are several statements found in a Purdue package inserts filed with the FDA that reference medical and scientific studies not found in the discovery adduced by the PEC that are specifically relevant to NAS Guardian Plaintiffs':

- a. "Female subjects have on average plasma oxycodone concentrations up to 25% higher than males on a body weight adjusted basis. The reason is not known".

PDD8003167492.

- b. "There are no well-controlled studies in women, but marketing experience does not include any evidence of adverse effects on fetuses following routine (short-term) clinical use of morphine sulfate products". PDD8003167730.

- c. "The ratio of umbilical venous and maternal concentration of levobupivacaine ranged from 0.252-0.303 after epidural administered of levobupivacaine cesarean section. These are within the range normally seen for bupivacaine".

PDD8003167704.

- d. Reference is made to assays finding no mutagenic impacts and to assays finding clastogenic impacts. Rat and rabbit studies are cited for the proposition that opioids are not teratogenic. These studies were not cited, named or footnoted.

PDD8003167495.

Such questions of medicine and science matter to claims being pursued by the NAS Guardian Plaintiffs. For example, if the package insert was inconsistent with the observations noted in the actual study that would present a common question of fact relevant to the risk of latent disease prong of a medical monitoring claim. Given that the Defendants have already

produced tens of millions of documents, answering the limited discovery attached should not be overly burdensome.²

Discovery Requests Currently in Dispute

Written discovery requests were initially propounded by NAS Guardian Plaintiffs pursuant to this Court’s scheduling order [Rec. Doc. 2738] on October 15, 2019. The written Discovery related to class certification is extremely limited, and fall into two categories:

1. Prescription records that relate to the specific plaintiffs in the four putative class certification cases; and
2. Documents Related to certain clinical studies conducted by Defendants. (*See* “Exhibits A, B, C, and D” of Dann Declaration).

Attempts to Resolve Outstanding Discovery Disputes

On October 24, 2019, Terry Henry sent a letter on behalf of most of the Defendants that took the following position:

“The Defendants identified in your discovery requests do not intend to serve formal responses to Plaintiffs’ discovery requests for the following reasons: (i) Judge Polster has not authorized Plaintiffs to conduct discovery; (ii) much of the discovery Plaintiffs seek is unrelated to class certification or is equally available to Plaintiffs; and (iii) Defendants have already produced a prodigious amount of discovery available to Plaintiffs”.

(*See* “Exhibit E” to the Dann Declaration October 24, 2019 Letter from Terry Henry, “Defendant’s Response to Plaintiff’s Discovery Requests”). (*See also* “Exhibit F” to the Dann Declaration October 24, 2019 Letter from Kevin Sadler on behalf of Asserto Therapeutics Inc).

NAS Guardian Plaintiffs’ Counsel accepted Defendants’ invitation to meet and confer and on Friday October 25, 2019. A conference call was conducted between Plaintiffs’ and

² The recent filing of bankruptcy by Defendant Purdue [Rec. Doc. 2609] will require Baby Plaintiffs to seek relief in the Bankruptcy Court to secure discovery from Purdue.

Defendants' Counsel in an attempt to find a resolution to this standoff on the issue. No resolution was reached. On October 28, 2019, Plaintiffs' Counsel sent a letter to Defendants' Counsel seeking clarification on their position, and requesting that Counsel for Defendants direct Counsel for NAS Guardian Plaintiffs to the Bates stamps or other identifying numbers of previously produced documents that Defendants believe are responsive the NAS Guardian Plaintiffs' requests. (See "Exhibit G" to the Dann Declaration).

On October 30, 2019, Defendants' Counsel sent correspondence again refusing to identify the documents requested. (See "Exhibit H" to the Dann Declaration, October 30, 2019 Letter from Terry Henry to Plaintiffs' Counsel). After extensive efforts at resolution, Defendants maintain their position that they are not obligated to direct Plaintiff's Counsel to the requested documents.

I. LAW AND ARGUMENT

Under the Federal Rules of Civil Procedure, parties may demand "any non privileged material that is relevant to any party's claim or defense," provided that the evidence "appears reasonably calculated to lead to the discovery of admissible evidence". Fed. R. Civ. P. 26(b)(1). A trial court may limit discovery where "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues". Fed. R. Civ. P. 26(b)(2)(C)(iii). *Superior Prod. P'ship v. Gordon Auto Body Parts*, 784 F. 3d 311, 320-21 (6th Cir. 2015).

In this case, Defendants have objected to producing key evidence, including prescription and other medical records directly related to the named Plaintiffs and documents related to

certain medical studies, all of which are necessary for the motion for class certification. Records of the individual Plaintiffs who are seeking to become class representatives have not been previously produced and are clearly relevant. These records are necessary for class certification because they establish that the Guardians who seek to represent the class are in the best position to do so.

With respect to the medical studies, NAS Guardian Plaintiffs have asserted claims for medical monitoring, which requires proof that the Defendants have tortiously exposed the Plaintiffs to a toxin which creates a risk for serious latent disease. Outstanding discovery, specifically requests medical and scientific documents in Defendants' possession, related to the negative health impacts associated with exposure to opioids in utero, which would inform an inquiry into the risk of latent negative health impacts and disease outcomes. One example of such medical and scientific documents would be those which relate to mare-offspring testing to determine any latent effects revealed in animal testing.

NAS Guardian Plaintiffs also seek certain medical studies that are directly relevant to class certification and have not been previously produced. While reference is made throughout Defendants' FDA filings to rat and rabbit studies that purportedly determined that opioids are not teratogenic, NAS Guardian Plaintiffs' Counsel are unable to locate those animal studies or any other mare-offspring scientific studies in the discovery documents to which the PEC provided access. Any such studies relied upon by the manufacturer are common evidence germane to the issue of substantial risk of latent disease associated with exposure to opioids in utero. To be clear, NAS Plaintiffs seek all medical and scientific documents described in the Plaintiffs' outstanding discovery requests and those requests are not limited to mare-offspring studies.

In addition to implicating the issues directly related to medical monitoring claims, the medical and scientific documents sought also implicate the NAS Guardian Plaintiffs' claims related to RICO and Civil Conspiracy because Defendants' have consistently attempted to advance scientific conclusions that appear to be inconsistent with published, generally accepted science. Plaintiffs' experts have identified numerous articles in medical and scientific journals that seem to directly contradict the representations of the Defendants in the above-mentioned Defendant submissions to the FDA. This apparent inconsistency between the Defendants' representations to the FDA and available medical literature frames a common question of fact that goes directly to the tort allegations that form the basis of the medical monitoring claims asserted.

Defendants generally claim that responsive documents have been produced to the PEC, but they refuse to specify which of the millions of documents it has produced are responsive to Plaintiffs' discovery requests. Instead, Defendants propose that Plaintiffs should sort through those documents themselves, without any guide or indication of which records are responsive and where those records are located. Despite a diligent and comprehensive search of the available records, NAS Guardian Plaintiff Counsel have been unable to locate any records responsive to these requests.

It is well settled that a defendant has an obligation to specifically identify the category and location of responsive documents, and that it is insufficient to simply direct the requesting party to an undifferentiated mass of documents. Federal Rule of Civil Procedure 33(d) provides that “[a] party may produce business records in lieu of responding to interrogatories when the answer may be ascertained from such records”. Fed. R. Civ. P. 33(d). However, Rule 33

requires that “[a] specification shall be in sufficient detail to permit the interrogating party to locate and to identify, as readily as can the party served, the records for which the answer may be ascertained.” *See Hillyard Enters., Inc. v. Warren Oil Co.*, No. 5:02CV329, 2003 U.S. Dist. LEXIS 27922, at *4 (E.D.N.C. Jan. 31, 2003). The purpose of the specificity requirement in 33(d)(1) is to prohibit “directing the interrogating party to a mass of business records. . . .” Fed. R. Civ. P. 33 Advisory Committee’s Note. A responding party “has the duty to specify, by category and location, the records from which answers to interrogatories can be derived” and may not simply direct the opposing party “to an undifferentiated mass of records.” .” *Hillyard Enters., Inc.*, 2003 U.S. Dist. LEXIS 27922, at *4 (quoting Fed. R. Civ. P. 33 advisory committee’s notes); *see also Minter v. Wells Fargo Bank*, N.A., 286 F.R.D. 273, 278-79 (D. Md. 2012); *Graske v. Auto-Owners Inc. Co.*, 647 F. Supp. 2d 1105, 1108 (D. Neb. 2009) (holding that production of seven thousand documents was not sufficient under 33(d)).

Consistent with Rule 33, and the advisory committee notes, Defendants should be required to specifically identify, by category and Bates stamp, the documents responsive to NAS Guardian Plaintiffs’ outstanding discovery requests.

III. CONCLUSION

The Court should grant NAS Plaintiffs’ motion to compel discovery.

Respectfully submitted,

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CERTIFICATE OF SERVICE

A copy of the foregoing was filed via the Court's electronic filing system on this 1st day of November, 2019. Notice of this filing will be sent by e-mail through the Court's electronic case-filing system to all Counsel of record.

/s/ Marc E. Dann

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